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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,205	05/15/2006	Ezio Bombardelli	2503-1186	5416

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EXAMINER	
CHEN, CATHERYNE	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
11/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/562,205	BOMBARDELLI, EZIO	
	Examiner	Art Unit	
	CATHERYNE CHEN	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendments filed on Nov. 13, 2009 has been received and entered.

Currently, Claims 1-5, 7-8 are pending. Claims 1-5, 7-8 are examined on the merits. Claims 6 and 9 are canceled.

The declaration of Ezio Bombardelii filed July 13, 2009 has been considered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 1-5, 7-8) in the reply filed on Jan 26, 2007 is acknowledged. The election of species is referred to Example 1 in the Specification, which are Salix rubra extract, Boswellia serrata extract, Green Tea extract, N-acetyl-glucosamine, Glucuronolactone, Enothera biennis oil.

Response to Arguments

The declaration under 37 CFR 1.132 filed July 13, 2009 is insufficient to overcome the rejection of claims 1-5 and 7-8 as set forth below.

The composition of Claim 1 is not commensurate in scope with the results on page 3 of the Affidavit because no amounts are claimed in Claim 1.

Therefore, the affidavit of the composition having better than additive effects is not found to be convincing.

Claim Rejections - 35 USC § 103

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147) in view of Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) for the reasons set forth in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

Foster teaches saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Saligenin is derived from salicin, which is the main component of Salix species (see page 231, right column, Studies on the Biopharmaceutical Quality and Pharmacokinetics, Chrubasik et al., 1998, Pain Digest, 8: 231-236).

However, it does not teach boswellic acid, procyanidins, N-acetyl-glucosamine, glucuronolactone, concentrations.

Taneja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5).

Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). The extract is used to treat condition of tissue inflammation, such as arthritis (column 3, lines 37-38, 54). Procyanidins can be isolated from green tea leaves, which are Camellia senesis (see Abstract, Nonaka et al., 1983, Chemical and Pharmaceutical Bulletin, 31, 3906-3914).

Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44).

Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating inflammation. Thus, one of ordinary skill in the art would have had a reasonable expectation that the combination of these compounds would have been additively beneficial for treating inflammation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on

the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

The references teach ingredients for treating inflammation. Thus, an artisan of ordinary skill would reasonably expect that ingredients to treat inflammation could be used as the types inflammation treatment composition taught by the references. This reasonable expectation of success would motivate the artisan to use saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, and D-glucuronolactone in the reference composition. Thus, using saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, and D-glucuronolactone is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for treatment of arthritis. However, the reference does teach the composition for treating inflammation, which is a symptom of arthritis. Foster teaches saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Taneja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5). Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to

about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44). Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Applicant argues that Charters does not teach that N-acetyl glucosamine is effective.

In response to Applicant's argument, N-acetyl glucosamine is effective for use with combating inflammation, specifically for the joints, which are areas affected by arthritis induced inflammation (see Charters, column 1, lines 11-13-14). Applicant's claimed amount is 10-500 mg of glucosamine. Charters teaches about 10-40 mg is

used (column 8, lines 63-64). Therefore, the claimed range is also taught, which indicates that the effective amount is also taught.

Applicant argues that Ronzio fails to teach procyanidins.

In response to Applicant's argument, Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). The extract is used to treat condition of tissue inflammation, such as arthritis (column 3, lines 37-38, 54). Procyanidins can be isolated from green tea leaves, which are Camellia senesis (see Abstract, Nonaka et al., 1983, Chemical and Pharmaceutical Bulletin, 31, 3906-3914). As long as the claimed ingredient is taught, it is irrelevant, where the ingredient is from.

Applicant argues that there is no reason to optimize the amount.

In response to Applicant's argument, Foster teaches saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Taneja et al. teaches gum resin of Boswellia serrata has been used for the treatment of arthritis (column 1, lines 9-11), at 10 g (column 9, line 14), ranging from 1% to 55% by weight (column 11, lines 66-67; column 12, lines 1-5). Ronzio et al. teaches phenolics contents from about 1-6 mg of catechins, which contains procyanidin (column 3, lines 26-28, 31). Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44). Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5,

Effect of glucuronic acid derivatives). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

MPEP 2144.05 Obviousness of Ranges

II. OPTIMIZATION OF RANGES

A. Optimization Within Prior Art Conditions or Through Routine Experimentation Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facieobvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 ("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the

references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molarproportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); In re Kulling, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997).

> Thus, through routine experimentation, "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." In other words, the claimed amounts were well within the purview of the ordinary artisan at the time the invention was made in an effort to optimize the desired results.

Applicant argues that there is synergistic effect.

In response to Applicant's argument, the composition of Claim 1 is not commensurate in scope with the results on page 3 of the Affidavit because no amounts are claimed in Claim 1.

Therefore, the affidavit of the composition having better than additive effects is not found to be convincing.

Claims 1-5, 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) as applied to claims 1-4 above, and further in view of Chilton (US 6107334) for the reasons set forth

in the previous Office Action, which is set forth below. All of Applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive.

The teachings of Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) are set forth above and applied as before.

The combination of Foster (1897, Reference-Book of Practical Therapeutics, vol. II, D. Appleton and Co., New York, page 147), Taneja et al. (US 5629351), Ronzio et al. (US 5762936), Charters et al. (US 6541045), Sato et al. (1967, Jap. J. Pharmacol., 17, 557-571) do not specifically teach oenthera biennis.

Chilton teaches dietary supplement for ameliorating inflammatory disorders such as arthritis (column 1, lines 6-7, 39-40) with GLA, which is obtainable from oils of evening primrose (column 5, lines 52-54; column 6, lines 45-46) or Oenthera biennis (see http://plants.usda.gov/java/profile?symbol=OEBI) and evening primrose is suitable as an ingestible pharmaceutical formulation (column 4, lines 15-16).

"It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose ...[T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted).

In the instant case, all of the above-listed ingredients were known for treating inflammation. Thus, one of ordinary skill in the art would have had a reasonable

expectation that the combination of these compounds would have been additively beneficial for treating inflammation.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for treating inflammation. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518.

The references teach the ingredients to treat inflammation. Chilton teaches dietary supplement for ameliorating inflammatory disorders such as arthritis (column 1, lines 6-7, 39-40) with GLA, which is obtainable from oils of evening primrose (column 5, lines 52-54; column 6, lines 45-46). Thus, an artisan of ordinary skill would reasonably expect that ingredients to treat inflammation could be used as the types inflammation treatment composition taught by the references. This reasonable expectation of success would motivate the artisan to use saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, D-glucuronolactone, and oils of evening primrose in the reference composition. Thus, using saligenin, procyanidins, boswellic acid, N-acetyl-D-glucosamine, D-glucuronolactone, and oils of evening primrose is considered an obvious modification of the references.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant for treatment of arthritis. However, the reference does teach the composition for treating inflammation, which is a symptom of arthritis. Foster teaches

saligenin was used to treat rheumatism, inflammation at 7-15 grains in the form of powder to be taken every hour or every two hours (page 147, Saligenin). Graus et al. teaches treatment of osteoarthritis, which involved inflammation (column 1, lines 16, 22-25), with procyanidins (column 4, line 11), boswellic acids by extracting Boswellia serrata at least 15%, between 10-1000 mg per day (column 4, lines 31-40). Charters et al. teaches anti-inflammatory drug of about 1% to about 5%, about 10 to about 40 mg of N-acetyl D-glucosamine (abstract, column 8, lines 50-51, 63-63) in capsule or tablets with pharmaceutical carrier (column 9, line 42-44). Sato et al. teaches anti-inflammatory activity of D-glucuronolactone at 200 mg/kg, 300 mg/kg, 400 mg/kg (page 566, Table 5, Effect of glucuronic acid derivatives). The amount of a specific ingredient in a composition that is used for a particular purpose (the composition itself or that particular ingredient) is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, optimization of general conditions is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Please see responses to arguments above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERYNE CHEN whose telephone number is (571)272-9947. The examiner can normally be reached on Monday to Friday, 9-5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Catheryne Chen
Examiner Art Unit 1655

/Michael V. Meller/
Primary Examiner, Art Unit 1655